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07/870,759	04/20/1992	JEAN-YVES CHENARD	03203.0006-0	2126
	90 04/21/2003 HENDERSON FARAI	ROW GARRETT & DUNNER	EXAMI	NER
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER [LLP 1300 I STREET, NW			JAGANNATHAN, VASUDEVAN SALEM	
WASHINGTON			ART UNIT	PAPER NUMBER

1714

DATE MAILED: 04/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

	L A sur Provide to N	A Carada					
•	Applicati n N .	Applicant(s)					
Office Action Commence	07/870,759	CHENARD ET AL.					
Office Action Summary	Examiner	Art Unit					
	Vasu Jagannathan	1714					
The MAILING DATE f this communication app Period for Reply	ears on the cover sneet with the c	orrespondence address					
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period v Failure to reply within the set or extended period for reply will, by statute.  - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be timed within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).					
Status	uoni 24 2002 (Panor No. 02)						
1) Responsive to communication(s) filed on <u>January</u>							
, <u> </u>	is action is non-final.	raccourtion as to the morite is					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims							
4) Claim(s) 324-366 is/are pending in the application							
	4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.							
6)⊠ Claim(s) <u>324-366</u> is/are rejected.							
7) Claim(s) <u>332,344,354 and 363</u> is/are objected		•					
<ul><li>8) Claim(s) are subject to restriction and/or</li><li>Application Papers</li></ul>	r election requirement.						
9)⊠ The specification is objected to by the Examine	r						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
Applicant may not request that any objection to the							
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action.							
12) The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) All b) Some * c) None of:							
1. Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
<ul> <li>3. Copies of the certified copies of the prior</li> <li>application from the International Bu</li> <li>See the attached detailed Office action for a list</li> </ul>	reau (PCT Rule 17.2(a)).	-					
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
a) The translation of the foreign language provisional application has been received.  15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachment(s)							
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal	y (PTO-413) Paper No(s) Patent Application (PTO-152)					

Introduction

The following action responds to the amendment filed January 21, 2003 in Paper No. 93.

Concurrently, with the filing of the amendment, the applicants had requested - and were granted

- a personal interview held on February 12, 2003 as recorded in Paper No. 94.

In the cited amendment:

a) The applicants canceled all the claims, 176-183, 193-198, 200-207, 209-217 and 219-

225 and filed a new set of claims, 324-366.

b) In these new claims, the applicants described specific tin (or Sn)-containing stabilizers

and stated that the amount of mercapto alkanol ester is such that it exceeds the amount required

to "saturate" the Sn component in the stabilizers.

In the interview, the applicants asserted that the above combination of limitations was not

disclosed in the prior art. However, an evaluation of prior art shows that it does disclose the

claimed stabilizers. Furthermore, the prior art also provides evidence that mercapto alkanol esters

are generally used in excess of what would be stoichiometrically required given the amount of

the Sn component in the stabilizers.

It is important to note that what the claims require is that the amount of mercapto alkanol

ester exceed a "saturation" amount with respect to, specifically, the Sn component in the

stabilizer rather than the stabilizer as a whole. As established below, such a requirement is

clearly disclosed in the prior art.

Art Unit: 1714

## **Specification**

1. The disclosure is objected to because of the following "informalities":

In "Example II" on page 22 of the instant specification the stated formula for "3-thioglyceryl myristate" is incorrect because a hydroxy (or OH) substituent is missing from the carbon atom that is in the  $\beta$ -position with respect to (or the  $2^{nd}$  carbon atom from) the SH group. Thus, applicants' erroneous formula reads "CH<sub>3</sub>(CH<sub>2</sub>)<sub>12</sub>COOCH<sub>2</sub>CHCH<sub>2</sub>SH" when, in fact, the correct formula is

Page 3

Appropriate correction is required.

[Note: It is understood that "CH<sub>2</sub>", "COO" and "OCO or OC(=O)" are often used as a form of "shorthand" notation for what ought to really be written as

respectively. Observe that the last of these notations/structures, "OCO or O(C=O)", is used in depicting a "reverse ester" linkage in mercapto alkanol esters:

O 
$$\parallel$$
 -S-(CH<sub>2</sub>)<sub>n</sub>-O(C=O)- or, equivalently, -S-(CH<sub>2</sub>)<sub>n</sub>-O-C-.]

Art Unit: 1714

### **Claim Objections**

2. Claims 332, 344, 354 and 363 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Page 4

[Note: This objection is separate from and is to be distinguished from the preceding objection to the specification.]

In particular, the species of mercapto alkanol ester identified as 3-thioglyceryl myristate in the above claims is not a proper embodiment of the mercapto alkanol ester represented by the formula RCOOR'SH, where R' is a C<sub>2</sub>-C<sub>18</sub> alkylene, in claims 327, 339, 349 and 358 from which depend claims 332, 344, 354 and 363, respectively.

Noting that R' =  $C_2$ - $C_{18}$  alkylene =  $(CH_2)_{2-18}$ , upon comparing the bracketed portions,  $\left[ \right]$ , in the formula for 3-thioglyceryl myristate (see, e.g., claim 332) with the RCOOR'SH formula (see, e.g., claim 327) as shown below, it is evident that since the bracketed portion in 3-thioglyceryl myristate is not an alkylene group due to the presence of the OH substituent, hence, 3-thioglyceryl myristate cannot be a proper embodiment of RCOOR'SH:

3-thioglyceryl myristate:

$$CH_{3}\text{-}(CH_{2})_{12}\text{-}C\text{-}O\text{-} \underbrace{\begin{pmatrix} H \\ | \\ CH_{2}\text{-}C\text{-}CH_{2} \\ | \\ OH \end{pmatrix}}_{CH} \text{-}SH$$

RCOOR'SH:

O 
$$\parallel$$
 R-C-O (CH<sub>2</sub>)<sub>2-18</sub> -SH.

### Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 324-366 are rejected under 35 U.S.C. 112, <u>first</u> paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically:

(a) With respect to claims 324-335 and 349-357, it is noted that the claimed metal i.e. tin (or Sn)-containing stabilizer (hereafter "stabilizer") having the formula

$$R_nSn(S)_y(SR')_x$$

where n = 1 or 2, x > 0 to 3 and x+2y = 4-n, describes some embodiments that are not supported by the original disclosure. While the following claimed embodiments are supported (see pages 15 and 16 of the specification) for certain values of n, x and y stated in parenthesis below each structure

$$R - Sn = S$$
  
 $|$   
 $SR'$   
 $(n = 1, x = 1, y = 1),$ 

$$R$$
|
 $R - Sn - SR'$ 
|
 $SR'$ 
( $n = 2, x = 2, y = 0$ )

and

however, other embodiments such as those arising e.g. from n = 1, x = 0.5, y = 1.25; n = 1, x = 2, y = 0.5; n = 2, x = 2.5 or 3, y < 0; etc., are unsupported.

Note that there is nothing mentioned in the claims that would prevent x and y from being fractional numbers. Furthermore, a negative value for y is meaningless. These issues are further discussed in paragraph 4 below.

- (b) With respect to claims 324-366, the statement regarding "a source of mercaptan exceeding that required to saturate the Sn component" in the independent claims is open-ended with respect to just how much of an excess amount of mercaptan relative to Sn is intended. From the specification, e.g., on page 20, lines 1-2, it is seen that the mercapto alkanol ester source is present in an amount of from "2 to 25 times" the amount of metal. There is no evidence that any ratio of mercapto alkanol ester to Sn is within the confines of the original disclosure. Hence, applicants' open-ended recitation does not fulfill the written description requirement.
- 4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 324-366 are rejected under 35 U.S.C. 112, <u>second</u> paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Application/Control Number: 07/870,759 Page 7

Art Unit: 1714

Specifically:

(a) With respect to claims 324-335 and 349-357, certain embodiments of the stabilizer, such as those identified in the 35 USC 112,  $1^{st}$  paragraph rejection above (see paragraph 3(a)), have chemically meaningless structures due to the presence of either fractional amounts of the S and SR' components in the formulas for the stabilizer or due to the fact that the subscript "y" is negative for such embodiments as those resulting from n = 2 and x = 2.5 or 3.

While it is recognized that some stabilizers in the prior art are represented by formulas containing fractional subscripts, however, it is understood that such formulas describe a multiplicity of statistically characterized "monomeric" units which are linked together to form a larger "polymeric" compound. Thus, Dorfelt et al., US 3,539,636, cited as a state-of-the-art reference, discloses at col. 1, lines 24 and 36 a compound of the formula "(RSnS<sub>1.5</sub>)<sub>n</sub>", where n is a whole number in the range of 2 to 8, having a fractional amount of the S component in the monomeric unit enclosed within parenthesis. When n = 2, for instance, Dorfelt's formula yields a chemically meaningful formula for thiostannoic anhydride, namely,

$$\begin{array}{ccc}
R - Sn - S - Sn - R. \\
\parallel & \parallel \\
S & S
\end{array}$$

However, this interpretation is inapplicable to the cited meaningless embodiments.

Futhermore, while page 15 in the applicants' specification describes a stabilizer having the formula  $(R^4SnZ_{1.5})_x$ , where Z is O or S and x is an integer from 3 to 20, this particular stabilizer, which involves multiple Sn atoms, is, however, not the one present in the applicants' claims since formula (I) in the claims involves but a single Sn atom.

- (b) With respect to claims 324 and 349, note that when the subscripts are such that n = 1, x = 3 or n = 2, x = 2, then y = 0 i.e. the "S" atom is no longer present in formula (I) in these claims with the result that these claims become identical to claims 336 and 358, respectively. Therefore, under the above-cited conditions there are redundant claims in this application.
- (c) With respect to claims 324-347 and 349-366, the use of the term "mercaptide ligand" or "mercaptide" to describe SR', especially when R' is not an alkyl group, brings applicants' terminology into conflict with that of prior art cited by the applicant's themselves in the present specification. It is clear from dependent claims, such as claim 325, that the terms mercaptide ligand and mercaptide denote a group such as a derivative of a carboxylic acid which is not an alkyl group. This is also confirmed on page 15 of the present specification where R<sup>6</sup> (as in SR<sup>6</sup>), which appears to be synonymous with R', is not limited to being just an alkyl group.

However, page 14 in the present specification refers to the "Encyclopedia of PVC", edited by Nass, in which, on page 315 in Table 3 of Chapter 9, a mercaptide is shown to have a formula where S is bonded to an alkyl (not any other) group. Hence, there is a conflict between what the applicants mean by mercaptide ligand or mercaptide vis-à-vis what the prior art signifies as represented by Nass. Note that a citation to the above-cited portion of the Encyclopedia has been inserted in the attached PTO-892 form and a copy of the same is being supplied to the applicants.

(d) With respect to claims 324-347 and 349-366, there is confusion because the metal containing stabilizer and the mercapto alkanol ester ingredients both use the same symbols, R and R', to denote different substituents in each ingredient. Thus, whereas "R" in the metal containing stabilizer is "an alkyl group" (see, e.g., claim 324), the same symbol as used in the

mercapto alkanol ester, RCOOR'SH, is not so limited (see, e.g., claim 327). And, compare RCOOR'SH, where R' is a  $C_2$ - $C_{18}$  alkylene (see, e.g., claim 327), with  $R_nSn(S)_y(SR')_x$  or  $R_nSn(SR')_x$  in which R' is not so limited (see, e.g., claim 325).

- (e) With respect to claims 325, 326, 337, 338, 350 and 359, it is not understood as to how the mercaptide ligand can be a "derivative" of, especially, a mercaptoacid ester or a mercaptoalcohol ester since these compounds are themselves derivatives of an acid or alcohol to begin with. In other words, what does a derivative of a derivative mean?
- (f) With respect to claim 330 (when compared with claim 329) and claim 342 (when compared with claim 341),
  - (1) the scope of each of these claims overlaps with the scope of the claim mentioned in parenthesis and is, thus, redundant when R contains 8 carbon atoms and
  - (2) the fact that in claims 330 and 342 R contains, e.g., 1 carbon atom, conflicts with the description of R being, e.g., an aryl group in claims 327 and 339 (from which depend claims 330 and 342) since, by definition, an aryl group cannot contain less than 6 carbon atoms.
- (g) With respect to claims 331, 332, 343, 344, 353, 354, 362 and 363, the use of "and" between the last two species or embodiments is improper. It would have been permissible if these claims were recited in Markush language format. Since they are not Markush claims, it is advised that "or" be used. In this connection, applicants' attention is directed to MPEP 2173.05(h) on "Alternative limitations".

Art Unit: 1714

(h) With respect to claims 333 and 355, the recitation of a weight percent of the mercapto

Page 10

alkanol ester without any indication what this weight percent is based on (total composition or

vinyl halide resin or etc.) renders the scope indefinite.

(i) With respect to claims 344, 345 and 361, there is no proper antecedent basis for the

recitation of "monocarboxylic acid", since none of the claims upon which the cited claims

depend recites this species of carboxylic acid.

(j) With respect to independent claim 348,

(1) there is no proper antecedent basis for the recitations of "The composition"

(line 1 of the claim) and "said metal containing stabilizer" (lines 5-6 of the claim)

and

(2) when component "(a)" in the composition is a mono alkyl tin bis(mercapto

alkanol ester) compound, it is observed that only 3 valencies of the tetravalent tin

are satisfied with the result that the tin has an improper dangling bond or an

unsatisfied valency.

**Double Patenting** 

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*,

422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, In re Thorington, 418 F.2d 528, 163

USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly

owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 324-348 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-16 of U.S. Patent No. 4,412,897 (of record) in view Harrison et al. US 4,093,484, Bjellqvist et al. US 4,278,518 and Sugahara et al. US 4,060,508 (all three of which are newly cited).

In the preceding action, mailed July 18, 2002 in Paper No. 92, an obviousness-type double patenting rejection was set forth using US 4,412,897 as the sole "reference". Although, generally, the scope of the present claims is not precisely the same as that of the claims originally rejected using this type of non-statutory rejection, nevertheless, after giving full consideration to applicants' response regarding the propriety of the rejection in Paper No. 93, it is the examiner's position that an obviousness-type double patenting rejection of the present claims is still warranted for the reasons given below.

### Establishing that the present claims are obvious over the patented claims

It is the examiner's position that the present claims which are directed to a composition, for stabilizing a vinyl halide resin, comprising a metal i.e. tin (or Sn)-containing stabilizer and a mercapto alkanol ester, where the mercapto alkanol ester provides a source of mercaptan exceeds that required to "saturate" the Sn component in the Sn-containing stabilizer, are obvious over the patented claims which are directed to a sterilized composition comprising a vinyl halide polymer and a stabilizing composition comprising an organotin stabilizer, a "mercaptan" and hydroquinone.

Application/Control Number: 07/870,759 Page 12

Art Unit: 1714

At the outset, note that to the extent that the scope of the present claims explicitly overlaps the scope of the claims of US 4,412,897, it is because:

(i) the stabilizer in the present claims is an "organotin" compound (since it contains Sn to organic alkyl (or R) and Sn to organic "mercaptide" (SR') bonds) which stands in a species-to-genus relationship with respect to the broad recitation of an "organotin" heat stabilizer in the patented claims (see, e.g., patented claim 11), and,

(ii) the presently claimed mercapto alkanol ester is identical to the particular "mercaptan" denoted as R(CH<sub>2</sub>)<sub>m</sub>COOR'SH, when m is 0, in the patented claims (see, e.g., patented claim 11), and, further,

(iii) the presently claimed requirement that the amount of mercapto alkanol ester exceed the amount required to "saturate" the Sn component of the stabilizer is met by dependent patented claims 12 and 13. To illustrate this, consider patented claim 12. It recites 0.1 to 5 weight % of organostannic (i.e. organotin) stabilizer compound and 0.1 to 6 weight % of "mercaptan" which, in one embodiment, is a mercapto alkanol ester as is evident from the formulas in independent claim 11 upon which claim 12 depends. Hence, in one instance, at least, the scope of the patented claim encompasses such relative amounts of stabilizer and mercaptan as, e.g., 0.1 weight % and 6 weight %, respectively. Clearly, the amount of mercaptan exceeds the amount of stabilizer by a factor of 60 and, hence, the amount of mercaptan must also be 60 times greater than, i.e. it exceeds the amount required to saturate, the amount of the Sn component in the stabilizer since the amount of Sn is necessarily less than the amount of stabilizer in which it is contained. A similar conclusion may be reached by a consideration of patented claim 13.

Art Unit: 1714

[Note: In the context of the present invention, such an analysis which indicates that the amount of mercapto alkanol ester is about 60 times greater than the amount of the Sn component in the stabilizer compound of US 4,412,897 clearly meets the claimed requirement of the amount of mercaptan exceeding the amount required to saturate the Sn-component of the stabilizer compound since page 20, lines 1-2 of the present specification informs us that the mercapto alkanol ester is present in an amount from "2 to 25 times" the amount of metal, i.e. Sn, in the stabilizer.]

The difference between the present claims and the claims of US 4,412,897 is that the patented claims involve a sterilized vinyl halide polymer composition which contains an additional ingredient beyond the organostannic compound and a mercapto alkanol ester, namely, hydroquinone.

Harrison et al. and Bjellqvist et al. teach that articles made from a vinyl halide polymer composition, such as PVC i.e. poly(vinyl chloride), are irradiated for the particular reason that it results either in useful sterilized surgical products (Harrison et al. at column 2, lines 20-21) or for the purpose of reducing undesirable monomer content (Bjellqvist at column 2, line 67 over to column 3, line 2). Sugahara et al., for their part, disclose stabilizer compositions for PVC (at column 15, line 15 ff.) which contain not only organotin compounds, which themselves further contain Sn to SR bonds at that (thus, see column 13, line 40 ff.), but also, additionally, hydroquinone compounds (at column 12, lines 35-37). From column 11, line 33 and column 12, lines 35-37 of Sugahara et al., it is evident that hydroquinones serve a useful function as "organic stabilizers" for chlorine containing polymers such as PVC. It will be observed that these

references share a common theme in that they all deal with vinyl halide polymer containing compositions.

Page 14

It is urged that in transiting from the patented claims to the present claims, it would have been obvious to one of ordinary skill in the art, to drop the requirement of sterilization by irradiation of a vinyl halide polymer containing composition if one did not desire to make surgical products or if one could tolerate a certain amount of residual monomer content, per Harrison et al. or Bjellqvist et al., and, further, to not utilize hydroquinone (as in Sugahara et al.) if the organotin stabilizer by itself or in combination with other stabilizers maintains its capacity to stabilize a vinyl halide polymer containing composition. According to patent law bearing on this point:

"By the omission of an element attended by corresponding omission of the function performed by that element, there is <u>no invention</u> if elements retained perform [the] same function as before" (emphasis added). <u>In re Application of John M. Porter</u>, 20 USPQ 298 (CCPA 1934).

The examiner's position is that after dropping the requirement of sterilization and the use of hydroquinone from the claims of US 4,412,897, what is retained is a stabilizer composition, such as that presently claimed, containing an organostannic compound and a mercapto alkanol ester and that these ingredients would continue to perform their original functions as stabilizers for a vinyl halide polymer, absent evidence to the contrary. Indeed, sterilization is an additional step that depends on what the intended "end use" of the final product is and, hence, can be obviously dispensed with depending on circumstances, and, absent evidence to the contrary,

Page 15

dropping the use of hydroquinone does not diminish the original stabilization capacities of the organostannic compound and mercapto alkanol ester.

It is important to note that the examiner's position will not be undermined by any argument that the additional presence of hydroquinone may enhance stabilization. Rather, the relevant issue in light of Porter is would the organostannic compound and mercapto alkanol ester continue to function as stabilizers even if hydroquinone is absent - and the answer to that is in the affirmative. In view of the above discussion, it would therefore have been obvious to one of ordinary skill in the art to modify the patented claims in the manner and for the motivation set forth above and thereby arrive at the subject matter of the present claims.

On pages 11-12 of their response in Paper No. 93, the applicants point out that because the patented claims in US 4,412,897 resulted from an application filed on October 9, 1981 which is subsequent to the earliest effective filing date of August 28, 1979 to which the present claims are entitled, and, because of alleged administrative delays which occurred during the prosecution of the present application and the chain of applications that preceded it, a two-way determination of obviousness is called for.

While it is true that "a two-way test is to applied only when the applicant could not have filed the claims in a single application and there is administrative delay" (see MPEP 804, page 800-23, August 2001 edition), however, for the reasons given below, it is asserted that the applicants have not met the above criteria that would technically require the Office to levy a twoway obviousness-type double patenting rejection.

Thus, note that:

(a) The applicants could clearly have filed the present claims in a single application since Example 2 in Table I at column 8 of US 4,412,897 is drawn to a composition containing an organotin stabilizer and a mercapto alkanol ester in such relative proportions that (as established previously above) the amount of the ester exceeds that required to saturate the tin component in the organotin stabilizer. This embodiment, in the absence of irradiation to sterilize the composition, is precisely what is being claimed in the present application.

(b) The "administrative delay" in prosecution seems to have resulted more from applicants' activities than by what the Office did. While one can debate as to what precisely constitutes "administrative delay", on a more pragmatic level there is useful guidance to be found on page 800-23 in the portion of the MPEP cited above according to which:

"The court [Federal Circuit] found that the one-way test is appropriate where applicants, rather than the Office, had significant control over the rate of prosecution of the application at issue. In support of its finding that the applicants were responsible for delaying prosecution of the application during the critical period, the court noted that the applicants had requested and received numerous time extensions in various filings."

In light of the above, the examiner consulted the file-wrapper records of the applications involved in the chain of applications that led to the present application. The chart on the following page shows the result of such an investigation.

Art Unit: 1714

Serial Number of Application	Activity	Date
06/254,313	Request for extension of time	5/3/83
Greatgrandparent	Ditto	6/8/83
application	Ditto	12/18/84
• •	Ditto	6/11/85
	Ditto	7/18/88
	Ditto	11/18/88
	Abandoned for purposes of filing a file-wrapper continuation	5/4/89
07/273,669	Request for extension of time	4/5/90
Grandparent	Ditto	10/31/90
application	Ditto	12/28/90
	Abandoned for purposes of filing a file-wrapper continuation	2/7/91
07/633,187	Request for extension of time	4/20/92
Parent application	Abandoned for purposes of filing a file-wrapper continuation	6/29/92

It is seen from the above that the present applicants obtained multiple extensions of time and abandoned multiple applications over a lengthy period of time. Hence, it is evident that the previously cited finding of the Federal Circuit regarding applicants' responsibility in causing prosecution delay would appear to be applicable in the present case. This then provides substance to the examiner's position that there is a good reason as to why a one-way test for obviousness is justified in the present instance.

Nevertheless, in the event that it is ultimately established that the present claims are to be subjected to a two-way showing of obviousness, the examiner is providing below the "second leg" of a two-way test, the first one having been already set forth above.

#### Establishing that the patented claims are obvious over the present claims

It is the examiner's position that the claims of US 4,412,897, which are directed to a sterilized composition comprising a vinyl halide polymer and a stabilizing composition comprising an organotin stabilizer, a mercaptan chosen from compounds having specific formulas and hydroquinone are obvious over the present claims which are directed to a composition, for stabilizing a vinyl halide resin, comprising a metal i.e. tin (or Sn)-containing stabilizer and a mercapto alkanol ester, where the mercapto alkanol ester provides a source of mercaptan exceeds that required to "saturate" the Sn component in the Sn-containing stabilizer.

Rather than reiterate the similarities and difference between the present claims and the patented claims, as well as those portions of Harrison et al., Bjellqvist et al. and Sugahara et al. that are relevant to the issues at hand, the reader is referred to the discussion set forth above for these particular aspects.

In light of the particular usefulness of providing a sterilized vinyl halide polymer containing composition either to make surgical products (as disclosed by Harrison et al.) or, by irradiation, to reduce undesirable monomer content in vinyl halide polymers (as taught by Bjellqvist et al.), and, further, in light of the recognized utility of hydroquinone as an organic stabilizer for a vinyl halide polymer (as described by Sugahara et al.), all of which were described above, it is urged that it would therefore have been obvious to one of ordinary skill in

the art to modify the presently claimed composition by the additional incorporation of a hydroquinone stabilizer component and, should a sterilized product or a monomer residue free

product be desired, to irradiate the claimed composition to make a useful product and thereby

arrive at the subject matter of the claims of US 4,412,897.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the

basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on

sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 324-326, 335-338, 347-351, 353-360 and 363-366 are rejected under 35

U.S.C. 102(b) as being anticipated by Kugele US 4,062,881 (of record).

It is noted that in applying this rejection, the scope of the cited claims with respect to the

mercapto alkanol ester of a carboxylic acid described to be component "(b)" (see, e.g., claim

324), has been interpreted to be such that the disclosure of those compounds in the prior art

whose structures are comprised either wholly or in part of such a mercapto alkanol ester is

presumed to be relevant in assessing the patentability of the claims. This presumption is

appropriate given that there is nothing in the above-cited claims that would limit their scope to

any specifically structured compound(s) beyond the requirement that component (b) be a

mercapto alkanol ester of a carboxylic acid.

The examiner's position is supported by the description of the structure of mercapto

alkanol ester given by the applicants on pages 8-13 of the instant specification. It is seen that as

Art Unit: 1714

long as a mercapto alkanol ester fragment is present, the structure can contain a variety of other moieties such as residues of dicarboxylic acids (page 9), polyalkylene oxides (page 8), silicone esters, polyamides and amino acids (all on page 10).

It is observed that the mercapto alkanol ester fragment is also present in some embodiments of component (a) (see, e.g., claim 326). But this poses no particular problem since Kugele discloses stabilizers containing such a fragment as explained below.

With that in mind, note that Kugele discloses tin containing stabilizers that are particularly useful with a vinyl halide polymer such as a vinyl chloride polymer. See, e.g., column 9, lines 45-49.

With respect to the claimed requirement of an "effective amount" (without further quantification) of composition for stabilization, given that the reference states that its composition functions as a stabilizer, it stands to reason that the reference composition must therefore be present in an amount that is effective to impart stabilization.

Kugele observes that mercapto esters which are derived from reactants where the mercapto group is present in the alcohol reactant have "significant advantages" in contrast to the situation where the acid reactant carries the mercapto group. One such significant advantage is that esters from mercapto alcohols impart "superior stabilizing properties for vinyl chloride polymers". See column 1, lines 25-35. Given the presence of mercapto alkanol esters in all of the instant claims, it is clear that Kugele's disclosure is of special relevance. It is also significant in view of the fact that in the prosecution history of the present application, and its chain of parent cases, the applicants had laid much emphasis on the importance of mercapto alkanol esters.

Art Unit: 1714

Particular attention is drawn to Kugele's "Sample 31" which is a stabilizer composition comprising dimethyltin bis(2-mercaptoethyl pelargonate) (say "A") and monomethyltin tris (2-mercaptoethyl pelargonate) (say "B") in a 1:2 weight ratio. See columns 27-28, especially the description given below Table VII.

Since A has the structure  $(CH_3)_2$ -Sn- $(S-CH_2-CH_2-O-C(=O)-(CH_2)_7-CH_3)_2$ , the requirement of a metal containing stabilizer of the form  $R_2Sn(SR')_2$  as described in component (a) in independent claim 324 or 349 (with n = 2, x = 2 and y = 0) and independent claim 336 or 358 (with n = 2 and x = 2), and, the requirement of a stabilizer which is a dialkyltin compound as described in independent claim 348 are clearly met. Thus A is being taken to correspond to the claimed component (a).

For the meaning of the notation "O-C(=O)" in the structure of A, reference is made to the "Note" in paragraph 1 on page 3 of this Office action.

Further, since B contains a 2-mercaptoethyl pelagonate fragment, whose structure is -S-CH<sub>2</sub>-CH<sub>2</sub>-O-C(=O)-(CH<sub>2</sub>)<sub>7</sub>-CH<sub>3</sub>, the requirement of a mercapto alkanol ester as described in component (b) in the cited claims is also clearly met. Taken in conjunction with the observation regarding the scope of the claims with respect to the claimed component (b), B is being taken to correspond to component (b).

Particular note should be made of the fact that since the weight ratio of the mercapto alkanol ester portion as contained in B to the tin (Sn) portion as contained in A is (651x2)/118.7 to 1, or 11 to 1, it is evident that in Kugele's composition the mercapto alkanol ester portion is present in stoichiometric excess relative to the tin component. This clearly meets the corresponding claimed requirement especially in light of the fact that page 20, lines 1-2 of the

Art Unit: 1714

present specification informs us that the mercapto alkanol ester is present in an amount from "2 to 25 times" the amount of metal (i.e. Sn) in the stabilizer.

It is observed that in computing the amount of mercapto alkanol ester portion in B, the amounts of methyl group and Sn component in B were <u>not</u> included in the calculation as is only proper in checking to see if Kugele meets the claimed limitation. The inclusion of the methyl group and Sn would, in fact, increase (i.e. "improve") the mercapto alkanol ester to Sn ratio. However, the examiner is describing the "worst case scenario" in order to demonstrate just how relevant the reference actually is. With respect to the numbers used in the above computation, 651 is the total formula weight of the tris(2-mercaptoethyl pelargonate) portion and 118.7 is the atomic weight of tin.

It is noted that since A and B both contain a 2-mercaptoethyl pelargonate fragment which is a 2-mercaptoalkanol ester of a carboxylic acid, Kugele evidently discloses the claimed subject matter as described in dependent claims 325, 326, 337, 338, 350, 351, 353, 359, 360 and 362. With respect to dependent claims 354 and 363, note the list of mercapto alkanol esters disclosed at column 6, line 60 over to column 7, line 44 of Kugele. With respect to the amount of the component "(b)" comprising a mercapto alkanol ester as claimed in dependent claims 355, 356, 364 and 365 attention is drawn to column 10, line 44 which discloses that Kugele's stabilizers are present to the tune of 0.2 % by weight relative to the polymer that is being stabilized. Since, as discussed above, Kugele's stabilizers contain a mercapto alkanol ester fragment and claims 355, 356, 364 and 365 are not limited to any specifically structured compounds, it is apparent that Kugele discloses the subject matter of these claims.

Art Unit: 1714

With respect to method claims, such as 349 and 358, since no particular steps are mentioned with regard to the use of the claimed composition to stabilize a vinyl halide resin, hence the reference's disclosure of the usefulness of its composition as a stabilizer for a vinyl halide resin suffices to meet such claims.

In view of the preceding discussion, it is evident that the cited present claims are anticipated by Kugele.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Note:

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 324-326, 335-338, 347-351, 353-360 and 363-366 are rejected under 35 U.S.C. 102(e) as being anticipated by Bohen et al. US 4,115,352 (newly cited).

It is noted that in applying this rejection, the scope of the cited claims with respect to the mercapto alkanol ester of a carboxylic acid described to be component "(b)" (see, e.g., claim 324), has been interpreted to be such that the disclosure of those compounds in the prior art whose structures are comprised either wholly or in part of such a mercapto alkanol ester is presumed to be relevant in assessing the patentability of the claims. This presumption is appropriate given that there is nothing in the above-cited claims that would limit their scope to

Art Unit: 1714

any specifically structured compound(s) beyond the requirement that component (b) be a mercapto alkanol ester of a carboxylic acid.

The examiner's position is supported by the description of the structure of mercapto alkanol ester given by the applicants on pages 8-13 of the instant specification. It is seen that as long as a mercapto alkanol ester fragment is present, the structure can contain a variety of other moieties such as residues of dicarboxylic acids (page 9), polyalkylene oxides (page 8), silicone esters, polyamides and amino acids (all on page 10).

It is observed that the mercapto alkanol ester fragment is also present in some embodiments of component (a) (see, e.g., claim 326). But this poses no particular problem since Bohen et al. discloses stabilizers containing such a fragment as explained below.

With that in mind, note that Bohen et al. discloses a two-component composition comprising tin containing stabilizers that are used with halogen resins such as polyvinyl chloride. See, e.g., column 11, lines 41-44 and 48.

With respect to the claimed requirement of an "effective amount" (without further quantification) of composition for stabilization, given that the reference states that its composition functions as a stabilizer, it stands to reason that the reference composition must therefore be present in an amount that is effective to impart stabilization.

Particular attention is drawn to Bohen et al.'s "Example 35" which is a two-component stabilizer composition comprising 1 part (by weight) of "MTMS" i.e. methyltin tris(2-mercaptoethyl stearate) (say "A") and 0.5 parts (by weight) of barium bis(2-mercaptoethyl stearate) (say "B") and in a 0.5:1 parts by weight ratio. See columns 15-16, especially the

continuation of Table I at columns 15-16, and, further, column 14, line 40 for the identification of MTMS.

Since A has the structure  $CH_3$ -Sn-(S- $CH_2$ - $CH_2$ -O-C(=O)-( $CH_2$ )<sub>16</sub>- $CH_3$ )<sub>3</sub>, the requirement of a metal containing stabilizer of the form  $RSn(SR')_3$  as described in component (a) in independent claim 324 or 349 (with n = 1, x = 3 and y = 0) and independent claim 336 or 358 (with n = 1 and x = 3), and, the requirement of a stabilizer which is a monoalkyltin compound as described in independent claim 348 are clearly met. Thus A is being taken to correspond to the claimed component (a).

For the meaning of the notation "O-C(=O)" in the structure of A, reference is made to the "Note" in paragraph 1 on page 3 of this Office action.

It is noteworthy that, in column 8, formula (V), Bohen et al. also discloses organotin stabilizers having the structure  $R^3Sn(Z)(SR^4)_a$  where when  $R^3$  is an alkyl group (column 8, line 31), Z is S i.e. sulfur (column 8, line 52), the subscript "a" is 1 (column 8, line 29) and  $R^4$  is a substituted hydrocarbon group containing a OC(=0) functionality (column 8, lines 47-49), then the resulting embodiment is none other than an embodiment of the presently claimed stabilizer of formula (I) in e.g. independent claim 324 or 349 with n = 1, x = 1 and y = 1 and where the Sn atom is joined to a S atom via a double bond so as to preserve the tetravalent nature of Sn. (The chemical structure for this particular claimed embodiment is shown by the second of the formulas on page 5 of this Office action.)

Further, since B contains a 2-mercaptoethyl stearate fragment, whose structure is -S-CH<sub>2</sub>-CH<sub>2</sub>-O-C(=O)-(CH<sub>2</sub>)<sub>16</sub>-CH<sub>3</sub>, the requirement of a mercapto alkanol ester as described in component (b) in the cited claims is also clearly met. Taken in conjunction with the observation

Art Unit: 1714

regarding the scope of the claims with respect to the claimed component (b), B is being taken to correspond to component (b).

Particular note should be made of the fact that since the weight ratio of the mercapto alkanol ester containing component B to the tin (Sn) portion as contained in A is (823.3x0.5)/118.7 to 1, or 3.5 to 1, it is evident that in Bohen et al.'s composition the mercapto alkanol ester portion is present in stoichiometric excess relative to the tin component. This clearly meets the corresponding claimed requirement especially in light of the fact that page 20, lines 1-2 of the present specification informs us that the mercapto alkanol ester is present in an amount from "2 to 25 times" the amount of metal (i.e. Sn) in the stabilizer.

With respect to the numbers used in the above computation, 823.3 is the formula weight of component B and 118.7 is the atomic weight of tin.

It is noted that since A and B both contain a 2-mercaptoethyl stearate fragment which is a 2-mercaptoalkanol ester of a carboxylic acid, Bohen et al. evidently discloses the claimed subject matter as described in dependent claims 325, 326, 337, 338, 350, 351, 353, 359, 360 and 362. With respect to dependent claims 354 and 363, note the mercapto alkanol esters disclosed at column 3, left-hand side, as well as at column 2, lines 20-24 of Bohen et al. which reveals that the hydrocarbyl portion, R², in "-X-(C=Y)R² contains 1-20 carbon atoms thereby encompassing a wide range of mercapto alkanol esters of carboxylic acids. With respect to the amount of the component "(b)" comprising a mercapto alkanol ester as claimed in dependent claims 355, 356, 364 and 365 attention is drawn to column 14, lines 15-16 and Example 35 in the continuation of Table I at columns 15-16 of Bohen et al. which discloses that the corresponding component identified as B is present in the amount of 0.5 parts per 100 parts of polyvinyl chloride

homopolymer i.e. to the tune of 0.5 % by weight relative to the polymer that is being stabilized. Since, as discussed above, Bohen et al.'s component B contains a mercapto alkanol ester fragment and claims 355, 356, 364 and 365 are not limited to any specifically structured compounds, it is apparent that Bohen et al. discloses the subject matter of these claims.

With respect to method claims, such as 349 and 358, since no particular steps are mentioned with regard to the use of the claimed composition to stabilize a vinyl halide resin, hence the reference's disclosure of the usefulness of its composition as a stabilizer for a vinyl halide resin suffices to meet such claims.

In view of the preceding discussion, it is evident that the cited present claims are anticipated by Bohen et al..

#### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

#### Note:

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 324-326, 335-338, 347-351, 353-360 and 363-366 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson US 2,707,178 (cited in an Information Disclosure Statement filed in the continuation case 08/399,216, now abandoned) in view of Leistner et al. US 2,641,588 (cited in the Information Disclosure Statement filed November 17, 1992 in Paper No. 69 in the present application).

It is noted that in applying this rejection, the scope of the cited claims with respect to the mercapto alkanol ester of a carboxylic acid described to be component "(b)" (see, e.g., claim 324), has been interpreted to be such that the disclosure of those compounds in the prior art whose structures are comprised either wholly or in part of such a mercapto alkanol ester is presumed to be relevant in assessing the patentability of the claims. This presumption is appropriate given that there is nothing in the above-cited claims that would limit their scope to any specifically structured compound(s) beyond the requirement that component (b) be a mercapto alkanol ester of a carboxylic acid.

The examiner's position is supported by the description of the structure of mercapto alkanol ester given by the applicants on pages 8-13 of the instant specification. It is seen that as long as a mercapto alkanol ester fragment is present, the structure can contain a variety of other moieties such as residues of dicarboxylic acids (page 9), polyalkylene oxides (page 8), silicone esters, polyamides and amino acids (all on page 10).

Wilson discloses stabilizers for polyvinyl chloride comprising "any primary stabilizer for vinyl chloride resins" (column 5, lines 55-56) and a secondary stabilizer which is a resinous ester of a mercapto alcohol and a dicarboxylic acid.

With respect to the claimed requirement of an "effective amount" (without further quantification) of composition for stabilization, given that the reference states that its composition functions as a stabilizer, it stands to reason that the reference composition must therefore be present in an amount that is effective to impart stabilization.

With respect to the primary stabilizer, while Wilson's invention broadly accommodates "any" stabilizer (column 5, line 55), note, in particular, column 5, line 58 where Wilson exemplifies such organotin compounds as dibutyltin dilaurate and dibutyltin maleate.

With respect to the resinous ester, note the table in Example IV at column 5 which depicts the ester to be a product of the reaction of mercapto ethanol with either succinic or adipic acid. Hence, this ester is, in fact, a mercapto alkanol ester. This is also confirmed by writing out the reaction as follows:

$$HS-CH_2-CH_2-OH + HO-(C=O)-(CH_2)_n-(C=O)-OH$$

$$HS-CH_2-CH_2-O-(C=O)-(CH_2)_n-(C=O)-O-CH_2-CH_2-SH + 2H_2O$$
,

where n=2 and 4 represent the residues of the succinic and adipic acid reactants, respectively. Although the above product may itself undergo further condensation type reactions, the crucial point that is of relevance here is that the end product(s) will always contain one or more mercapto alkanol ester fragments denoted by  $-S-CH_2-CH_2-O-(C=O)$ - in the above structure. Hence, Wilson teaches component (b) in the cited present claims.

Additionally, note column 5, line 81 over to column 6, line 3 which reveals that Wilson's mercapto alkanol ester is "advantageously employed with all vinyl chloride compositions". This clearly provides a broad range for the applicability of Wilson as a reference especially against claims containing compounds comprised of mercapto alkanol esters. Equally significantly, it is

Art Unit: 1714

mentioned in the above cited portion of Wilson that mercapto alkanol esters have been found to be "so unexpectedly efficient" that only small amounts need be used. It is apparent that well before the present applicants Wilson had already established the significance of compounds comprising mercapto alkanol esters in functioning in relatively small amounts as efficient costabilizers for vinyl chloride resins.

Although Wilson's examples in columns 3 to 5 show the use of lead silicate rather than an organotin compound as a primary stabilizer, nevertheless, the examples are useful in acting as a general indicator of the relative amount of primary stabilizer. Thus, the examples show that 2 parts of primary stabilizer are used. Further, column 2, line 70 discloses the use of 0.01 to 5 weight % of secondary stabilizer relative to the vinyl chloride resin. Hence, in a composition containing 100 parts of polyvinyl chloride (such as shown in the Examples), the ratio of 0.01 to 5 parts of mercapto alkanol ester secondary stabilizer to the amount of Sn contained in, say, 2 parts of dibutyltin dilaurate disclosed by Wilson as the primary stabilizer, yields a ratio of 0.01 to 5 parts of mercapto alkanol ester to 0.37 parts of Sn in dibutyltin dilaurate [obtained from (118.7\*2/630.7), where 118.7 is the atomic weight of Sn and 630.7 is the formula weight of dibutyltin dilaurate,  $(C_4H_9)_2Sn(OOCC_{11}H_{23})_2$ ] or a ratio of 0.03 to 13.5: 1. It is evident that Wilson's composition has the mercapto alkanol ester portion being present in stoichiometric excess, in one embodiment by as much as 13.5 times, relative to the tin component. This clearly meets the corresponding claimed requirement especially in light of the fact that page 20, lines 1-2 of the present specification informs us that the mercapto alkanol ester is present in an amount from "2 to 25 times" the amount of metal (i.e. Sn) in the stabilizer.

Art Unit: 1714

The difference between the present claims and Wilson is that Wilson's primary stabilizers as exemplified by dibutyltin dilaurate and dibutyltin maleate lack a mercaptide ligand in contrast to the organotin stabilizers in the present claims with the structures RSn(SR')<sub>3</sub> and R<sub>2</sub>Sn(SR')<sub>2</sub>.

Leistner et al. '588 informs us that when it comes to stabilization of polyvinyl chloride resins, organotin stabilizers such as "dibutyltin maleate or the corresponding dilaurate" (i.e. the ones disclosed by Wilson) have various disadvantages such as inefficiency, instability, processing difficulties, etc.. See column 1, lines 7 and 12-26. According to Leistner et al. '588, organotin stabilizers containing mercaptide ligands (referred to as "tin mercaptides" by Leistner et al. '588) and having the formula  $(R'S)_xSnR^2_{4-x}$ , x = 1 to 4, are "more effective" in overcoming the above mentioned disadvantages as compared to dibutyltin maleate or the corresponding dilaurate. See column 1, lines 29-35. It will be noted that Leistner at al. '588's organotin stabilizers are identical to the presently claimed stabilizers when the subscript x = 1 or 2 in the above formula.

With respect to method claims, such as 349 and 358, since no particular steps are mentioned with regard to the use of the claimed composition to stabilize a vinyl halide resin, hence the reference's disclosure of the usefulness of its composition as a stabilizer for a vinyl halide resin suffices to meet such claims.

Since Leistner et al. '588 provides a clear cut motivation to substitute organotin stabilizers having the same structure as those in the present claims instead of the relatively less effective dibutyltin maleate or dilaurate in the composition disclosed by Wilson, it would therefore have been obvious to one of ordinary skill to do so and thereby arrive at the claimed invention.

Art Unit: 1714

9. Claims 324-326, 335-338, 347-351, 353-360 and 363-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leistner et al. US 2,870,182 (cited in an Information Disclosure Statement filed in the continuation case 08/399,216, now abandoned) or Mack et al. US 2,914,506 (newly cited) or Molt US 3,931,263 (of record) any one of which in view of Shoemaker et al. US 2,460,436 (newly cited).

It is noted that in applying this rejection, the scope of the cited claims with respect to the mercapto alkanol ester of a carboxylic acid described to be component "(b)" (see, e.g., claim 324), has been interpreted to be such that the disclosure of those compounds in the prior art whose structures are comprised either wholly or in part of such a mercapto alkanol ester is presumed to be relevant in assessing the patentability of the claims. This presumption is appropriate given that there is nothing in the above-cited claims that would limit their scope to any specifically structured compound(s) beyond the requirement that component (b) be a mercapto alkanol ester of a carboxylic acid.

The examiner's position is supported by the description of the structure of mercapto alkanol ester given by the applicants on pages 8-13 of the instant specification. It is seen that as long as a mercapto alkanol ester fragment is present, the structure can contain a variety of other moieties such as residues of dicarboxylic acids (page 9), polyalkylene oxides (page 8), silicone esters, polyamides and amino acids (all on page 10).

Any one of the above cited primary references (viz. Leistner et al. '182, Mack et al., Molt) discloses stabilizer compositions for vinyl chloride resins. In Leistner et al. '182 the composition comprises organotin compounds of the formula R<sub>n</sub>SnX<sub>4-n</sub>, where n is an integer from 1 to 3 and, in one embodiment, R and X are an alkyl group and a mercapto alkanol ester

group, respectively. See column 1, line 27 and column 3, lines 49-50. In Mack et al. the composition contains organotin compounds of the formula  $R_n Sn(SR')_{4-n}$ , where n is 2 or 3. See column 1, lines 60-63 and lines 42-43. In Molt the composition comprises tin stabilizers having the formulas  $RSn(SR')_3$  and  $R_2Sn(SR')_2$ . Thus note the structures of the "ultimate" reaction products below Example 7 in columns 11-12 and just above line 50 in column 14. It is evident that each one of these references discloses an organotin stabilizer compound encompassed by the scope of the present claims.

With respect to the claimed requirement of an "effective amount" (without further quantification) of composition for stabilization, given that the reference states that its composition functions as a stabilizer, it stands to reason that the reference composition must therefore be present in an amount that is effective to impart stabilization.

Attention is directed to the following:

Example 7 at column 3 of Leistner et al. '182 which discloses the use of a dioctyl phthalate which is a known plasticizer for vinyl chloride resins. In this example, the plasticizer is present in the amount of 50 parts to 2 parts of the organotin compound.

Column 4, line 42 of Mack et al. which mentions the use of conventional plasticizers and column 5, line 35 in Example 1 which discloses a dioctyl phthalate plasticizer. In this example, the plasticizer is present in the amount of 100 g to 2 g of the organotin compound.

Column 7, lines 6-7 of Molt which names typical plasticizers such as di-2-ethylhexyl phthalate. Lines 5 and 10 of this column disclose 30 to 150 parts of plasticizer and 0.01-10 % by weight of the organotin compound per 100 parts of halogen resin.

It is immediately evident that the plasticizer amount exceeds by factors of 10 the amount of organotin compound and, hence, it also exceeds the amount of the Sn component in that organotin compound since the amount of Sn is necessarily less than the amount of organotin compound in which it is contained.

The difference between the present claims and any one of the cited primary references is the requirement in the claims of a mercapto alkanol ester of a carboxylic acid present in an amount exceeding that required to saturate the Sn component in the organotin compound.

Shoemaker et al. discloses that mercapto alcohol esters of polybasic acids "present a considerable advantage over prior art organic ester plasticizers." See column 1, lines 42-44. From the structural formulas for the mercapto alcohol esters as shown in claims 9 and 10 in column 6, it is evident that Shoemaker et al. describes the mercapto alkanol ester in the cited present claims. Column 1, lines 32-33 indicates that by "prior art organic ester plasticizers" what are meant are phthalate esters.

With respect to method claims, such as 349 and 358, since no particular steps are mentioned with regard to the use of the claimed composition to stabilize a vinyl halide resin, hence the reference's disclosure of the usefulness of its composition as a stabilizer for a vinyl halide resin suffices to meet such claims.

It is urged that in view of the clear cut motivation given by Shoemaker et al. to use mercapto alcohol esters, i.e. mercapto alkanol esters, instead of the conventional phthalate ester plasticizers, it would therefore have been obvious to one of ordinary skill in the art to substitute mercapto alcohol esters instead of the phthalate ester plasticizers in the inventions of any one of the primary references and, in light of the relative excess of plasticizer relative to the Sn

component in the organotin compound as discussed previously, thereby arrive at the claimed invention.

10. Claims 324-366 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kugele US 4,062,881 (of record) in view of Jennings et al. US 3,764,571 (cited in an Information Disclosure Statement filed in the continuation case 08/399,216, now abandoned).

Pertinent portions of the disclosure of Kugele, as described in the rejection in paragraph 6 above, are hereby incorporated by reference.

Attention is drawn to Example 48 in column 21 of Kugele which discloses a mixture of 181.5 g of an organotin stabilizer, which is methylthiostannoic acid, (CH<sub>3</sub>)Sn(=S)OH, and 408 g of a mercapto alkanol ester, which is 2-mercaptoethyl caprylate, HS-CH<sub>2</sub>-CH<sub>2</sub>-O-C(=O)-(CH<sub>2</sub>)<sub>6</sub>-CH<sub>3</sub>, the latter corresponding to component (b) in the present claims. It will be observed that 2-mercaptoethyl caprylate is one of the embodiments of a mercapto alkanol ester that falls within the compass of the dependent present claims 327-331, 340-343, 352, 353, 361 and 362.

For the meaning of the notation "O-C(=O)" in the structure of 2-mercaptoethyl caprylate reference is made to the "Note" in paragraph 1 on page 3 of this Office action.

Since the amount of Sn in 181.5 g of the methylthiostannoic acid stabilizer is 117.9 g (as computed from (118.7\*181.5/182.7) where 118.7 is the atomic weight of Sn and 182.7 is the formula weight of methylthiostannoic acid), hence it is seen that the weight ratio of 408 g of 2-mercaptoethyl caprylate to Sn is 408:117.9 or 3.5:1 which clearly meets the corresponding claimed requirement that the mercapto alkanol ester portion is present in stoichiometric excess relative to the tin component especially in light of the fact that page 20, lines 1-2 of the present

Art Unit: 1714

specification informs us that the mercapto alkanol ester is present in an amount from "2 to 25 times" the amount of metal (i.e. Sn) in the stabilizer.

With respect to the claimed requirement of an "effective amount" (without further quantification) of composition for stabilization, given that the reference states that its composition functions as a stabilizer, it stands to reason that the reference composition must therefore be present in an amount that is effective to impart stabilization.

Additionally, note should be made of column 10, lines 42-43 of Kugele which discloses that the amount of tin stabilizer, which it may be observed has incorporated in it the mercapto alkanol ester component due to a reaction between the Sn-containing stabilizer and the mercaptoalkanol ester compound, is 0.01 to 10 % by weight of the polymer being stabilized. Since the amount of incorporated mercapto alkanol ester cannot exceed 0.01 to 10 % by weight, it is deemed, therefore, that this would clearly encompass the claimed amount of mercapto alkanol ester of 0.01 to 5 % by weight as stated, e.g., in claims 333, 334, 345, 346, 355, 356, 364 and 365.

The difference between the present claims and Kugele is the requirement in the claims of an organotin stabilizer of the formula  $R_nSn(S)_y(SR')_x$  or  $R_nSn(SR')_{4-n}$  where n=1 or 2, x>0 to 3 and x+2y=4-n, in contrast to the stabilizer of the formula (CH<sub>3</sub>)Sn(=S)OH in the cited present Example 48 of Kugele.

Jennings et al. discloses organotin stabilizer containing compositions where the organotin component is characterized by Sn-S and Sn-C bonds, where S and C are carbon and sulfur, respectively. See, e.g., column 3, lines 10-15. Examples of such stabilizers as those shown, e.g., in column 3, line 36, column 4, lines 1-5 and column 5, line 25, reveal that Jennings et al.'s

Art Unit: 1714

stabilizers are very similar to the stabilizers of the present claims and Kugele. Moreover, according to column 1, lines 4-10, such stabilizers are "well-known" to be useful in the context of stabilizing vinyl halide resins. It appears that Jennings et al. is significantly relevant in assessing the patentability of the present claims.

Particular attention is drawn to Examples 28-38 in Table VII at column 19 of Jennings et from organotin al. which it is seen that such compounds say, monobutyltintris(isooctylthioglycolate), C<sub>4</sub>H<sub>9</sub>Sn(SCH<sub>2</sub>COO*i*C<sub>8</sub>H<sub>17</sub>)<sub>3</sub>, in Example 33, dibutyltin dilaurylmercaptide,  $(C_4H_9)_2Sn(SC_{12}H_{25})_2$ , in Example 36 and butylthiostannoic acid,  $(C_4H_9)Sn(=S)OH$ , in Example 38 are equivalent and interchangeable for use as organotin stabilizers. Indeed the last column of Table VII shows that these compounds are about equally effective in imparting similar heat stability values for compositions containing them. The equivalence or interchangeability of dibutyltin dilaurylmercaptide and butylthiostannoic acid is further emphasized in the last line of column 19, last line over to column 20, line 2 of Jennings et al. Furthermore, the organotin compounds in Examples 33 and 36 of Jennings et al. fall within the scope of the organotin stabilizers in the present claims.

Given that the methythiostannoic acid, (CH<sub>3</sub>)Sn(=S)OH, in Example 48 of Kugele is very closely related as a structural homolog to the butylthiostannoic acid, (C<sub>4</sub>H<sub>9</sub>)Sn(=S)OH, of Jennings et al. and further in view of the equivalence or interchangeability of butylthiostanoic acid and monobutyltintris(isooctylthioglycolate) or dibutyltin dilaurylmercaptide (the latter two of which clearly fall within the scope of the present claims with respect to the metal-containing stabilizer) as taught by Jennings et al., it is urged that it would therefore have been obvious to one of ordinary skill in the art to have substituted monobutyltintris(isooctylthioglycolate) or

dibutyltin dilaurylmercaptide instead of methythiostannoic acid in Example 48 of Kugele with the reasonable expectation of providing a useful stabilizer composition and thereby arrive at the claimed invention.

With respect to method claims, such as 349 and 358, since no particular steps are mentioned with regard to the use of the claimed composition to stabilize a vinyl halide resin, hence the reference's disclosure of the usefulness of its composition as a stabilizer for a vinyl halide resin suffices to meet such claims.

#### Citation of Relevant Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's 11. disclosure.

Dorfelt et al., US 3,539,636, is cited for its disclosure of organotin compounds having the formula (RSnS<sub>1.5</sub>)<sub>n</sub>. Reference to Dorfelt et al. is made in paragraph 4 of this Office action.

#### **Response to Arguments**

Applicant's arguments filed January 21, 2003 in Paper No. 93 have been fully considered 12. but they are not persuasive.

Specifically, regarding the obviousness-type double patenting rejection, applicants' arguments that the present claims could not have been filed earlier in a single application and that the "unreasonable delay" in the prosecution was not the applicants' fault are challengeable. For the reasons spelled out in the presently set forth obviousness-type double patenting rejection, it is urged that in the particular fact circumstances of this case there is really no proper basis to

Art Unit: 1714

ask for a two-way test. Nevertheless, in this Office action the examiner has responded with such

a test.

On pages 12-16 of their response, the applicants' opinion is that, in any event, an

obviousness-type double patenting rejection is "improper" in this case. The examiner disagrees.

As set forth in this Office action, the examiner has applied an obviousness-type double patenting

rejection based on a combination of "references" that does provide a proper basis for holding the

present claims to be rendered obvious over the claims of U.S. Patent No. 4,412,897.

With respect to the arguments regarding the applied prior art, it is noted that due to the

fact that applicants amended the claims, the examiner has given rejections using newly cited

prior art and/or new arguments in applying art of record.

In part due to the complexity of the issues involved in this application and, in part, based

on applicants' request during the Interview of February 12, 2003, the present Office action is a

non-final communication.

Any inquiry concerning this communication should be directed to Vasu Jagannathan at

telephone number (703)306-2777.

Cam Taganathan VASU JAGANNATHAN SUPERVISORY PATENT EXAMINER

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